UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC., *et al.*, Plaintiffs, v. SANDOZ, INC, Defendant.	Lead Civil Action No. 07-2762 (JAP) (consolidated case) **OPINION**

PISANO, District Judge.

Presently before the Court are motions by Fresenius Kabi Oncology plc and Dabur Pharma Limited (together "Dabur") for summary judgment of noninfringement[1] of United States Patent No. 5,716,988 (the "'988 patent") and United States Patent No. 5,290,961 (the "'961 patent"). Plaintiffs Sanofi-Aventis U.S. LLC, Sanofi-Aventis, Debiopharm, S.A. (together "Sanofi") oppose both motions and have cross-moved for summary judgment of infringement as to the '961 patent. For the reasons set forth below, all of the motions are denied.

I. Background

The Court will presume the parties' familiarity with the background facts of this litigation and summarizes only the facts pertinent to the instant motions.

[1]Dabur moves for summary judgment for noninfringement of claims 1 and 3-6 of the '988 patent. In response, Plaintiffs state that they are asserting claims 4-6 against Dabur. Because claims 4-6 are the only claims in controversy, this decision is directed only to those claims.

A. The '988 Patent

The '988 patent, which is entitled "Pharmaceutically Stable Preparation of Oxaliplatinum," concerns "pharmaceutically stable" preparations of oxaliplatin for administration parenterally. *See* '988 Patent, col. 1, lines 5-6. The stated objective of the '988 patent is to "obtain an injectable solution of oxaliplatinum which would be ready to use and which, furthermore, would remain pharmaceutically stable before use for an acceptable period of time according to recognized standards." '988 Patent, col. 2, lines 9-11.

Claim 4, which depends on claim 1,[2] reads as follows:

> [A pharmaceutically stable preparation of oxaliplatinum for the administration by the parenteral route, consisting of a solution of oxaliplatinum in water at a concentration of 1 to 5 mg/ml and having a pH of 4.5 to 6, the oxaliplatinum content in the preparation being at least 95% of the initial content and the solution remaining clear, colorless and free of precipitate after storage for a pharmaceutically acceptable duration of time] in the form of an aqueous solution of oxaliplatinum ready to be used and contained in a hermetically sealed container.

'988 Patent, col. 5, lines 13-15. Claim 5 requires that the container "contain an active unit dose of 50 to 100 mg of oxaliplatinum, which can be administered by infusion." *Id.*, lines 17-18. Claim 6 requires that "container is a glass vial for pharmaceutical use and is closed with a stopper of which, at least, the surface extending inside the vial is inert with respect to said

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[2] Claim 1 of the '988 patent, reads as follows:

> A pharmaceutically stable preparation of oxaliplatinum for the administration by the parenteral route, consisting of a solution of oxaliplatinum in water at a concentration of 1 to 5 mg/ml and having a pH of 4.5 to 6, the oxaliplatinum content in the preparation being at least 95% of the initial content and the solution remaining clear, colorless and free from precipitate after storage for a pharmaceutically acceptable duration of time.

'988 Patent, col. 4, line 66 to col. 5 line 6.

solution." *Id.*, lines 20-24.

At issue with respect to the instant motion is the use of the phrase "consisting of" in claim 1. According to Dabur, this phrase limits the invention to formulations that include only oxaliplatin and water, and Dabur asserts that the claims should be construed as being limited to "[f]ormulations that include oxaliplatin and water and that do not include any other components." Under this construction, because Dabur's oxaliplatin product contains oxaliplatin, water and sodium succinate,[3] which Dabur claims acts as a buffer, Dabur contends that its product does not infringe the '988 patent. Dabur Brf. 9-10.

B. The '961 Patent

The '961 patent, entitled "Platinum Compound and Process of Preparing Same," concerns a process for making oxaliplatin that includes a step for removing contaminants, resulting in oxaliplatin that is substantially free from impurities. Claim 1 of the '961 patent recites:

> A process of preparing a cis-platinum (II) complex of a 1,2-cyclohexanediamine isomer designated by a general formula (I)
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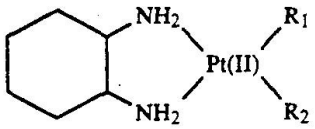
> 
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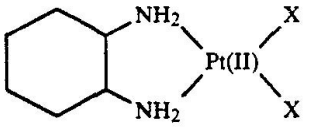
> 
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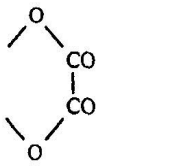
> (in the formula, the conformation of 1,2-cyclohexanediamine is cis, trans-d or trans-1-isomer, and R_1 and R_2 form with each other a circular group selected from the group consisting of the formulae (V), (VI), (VII), (VIII), (IX) and (X))

[3]Dabur has also added sodium hydroxide to its formulation, but its moving brief focuses only on succinic acid.



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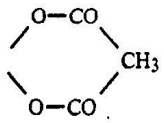

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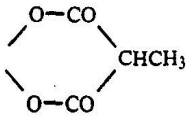

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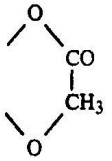

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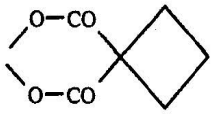

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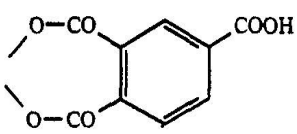

X

> which comprises adding to a dihalogen compound of a cis-platinum (II) complex of a 1,2-cyclohexanediamine isomer designated by a general formula (II), wherein X is a halogen, a silver ion solution containing not less than two equivalents of silver in respect to the compound (II), removing silver chloride and/or silver bromide, **adding to the solution sodium iodide and/or potassium iodide to convert the unreacted compound (II), the by-products of the compound (II) and an unreacted silver ion to their iodine compounds followed by the removal thereof** and thereafter adding the corresponding organic dibasic acid of the formulae (V), (VI), (VII), (VIII), (IX) and (X) to the remaining platinum complex.

'961 patent, Claim 1 (emphasis supplied). Dabur seeks summary judgment of noninfringement of claim 1, alleging that in producing its oxaliplatin product, at no point in the process does it add

sodium iodide or potassium iodide as is done in the claimed invention. Sanofi has cross-moved for summary judgment of infringement, alleging not that Dabur literally infringes the '961 patent, but rather alleging that Dabur infringes under the doctrine of equivalents.

II. Analysis

A. Summary Judgment Standard

A court shall grant summary judgment under Rule 56(c) of the Federal Rules of Civil Procedure "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The substantive law identifies which facts are critical or "material." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A material fact raises a "genuine" issue "if the evidence is such that a reasonable jury could return a verdict" for the non-moving party. *Healy v. N.Y. Life Ins. Co.*, 860 F.2d 1209, 1219 n.3 (3d Cir. 1988).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party makes this showing, the burden shifts to the non-moving party to present evidence that a genuine fact issue compels a trial. *Id.* at 324. In so presenting, the non-moving party may not simply rest on its pleadings, but must offer admissible evidence that establishes a genuine issue of material fact, *id.*, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

The Court must consider all facts and their logical inferences in the light most favorable to the non-moving party. *Pollock v. American Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986). The Court shall not "weigh the evidence and determine the truth of the matter," but need

determine only whether a genuine issue necessitates a trial. *Anderson*, 477 U.S. at 249. If the non-moving party fails to demonstrate proof beyond a "mere scintilla" of evidence that a genuine issue of material fact exists, then the Court must grant summary judgment. *Big Apple BMW v. BMW of North America*, 974 F.2d 1358, 1363 (3d Cir. 1992).

B. Fact Issues Preclude Summary Judgment as to '988 Patent

As stated above, the issue on this motion as to the '988 patent centers on the term "consisting of" as it appears in claim 1. It is true, as Dabur notes, that "[t]he phrase 'consisting of' is a term of art in patent law signifying restriction and exclusion." *Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, 482 F. Supp. 2d 390, 433 (D.N.J. 2007), *aff'd in part, rev'd in part on other grounds,* 518 F.3d 1353 (Fed. Cir. 2008) (quoting *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1382-83 (Fed. Cir. 2000). Said another way, "'consisting of' means these-and-only-these-options." *Id.* Because "'consisting of' is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim," Dabur argues that the invention of the '988 patent may only contain oxaliplatin and water. *See id.*, quoting *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004). Dabur's formulation of its oxaliplatin product contains a chemical that Dabur alleges acts as a"buffer," therefore, Dabur asserts that its product cannot infringe the '988 patent.

However, while the term "consisting of" does limit a claimed invention, "it does not limit aspects unrelated to the invention." *Norian Corp*, 363 F.3d at 1331. In *Norian Corp.*, for example, the invention was a kit containing certain specified chemicals. The accused product contained the claimed chemicals, however, the defendant added a spatula to its kit. The Court of Appeals for the Federal Circuit reversed a grant of summary judgment of noninfringement,

explaining that:

> While the term "consisting of" permits no other chemicals in the kit, a spatula is not part of the invention that is described. *Cf. Mannesmann Demag Corp. v. Engineered Metal Prods.*, 793 F.2d 1279, 1282-83 (Fed. Cir. 1986) ("The presence of additional elements is irrelevant if all the claimed elements are present in the accused structure."). ... Infringement is not avoided by the presence of a spatula, for the spatula has no interaction with the chemicals, and is irrelevant to the invention.

Id. at 1332. As such, the Court rejects Dabur's proposed claim construction to the extent that it proposes to limit aspects unrelated to the invention of the '988 patent. Therefore, in the present case, in order to determine the underlying question of infringement, the threshold question is whether the succinic acid added to Dabur's formulation is relevant or related to the invention claimed.[4] *See id.*

Dabur alleges that the succinic acid it adds to its oxaliplatin formulation functions as a buffer, *i.e.*, makes it "more resistant to change in pH than without it." Dabur Brf. at 3. It points to experiments it conducted and submitted to the Food and Drug Administration ("FDA") in response to the FDA's request for data demonstrating succinic acid's function as a buffer. *See* Declaration of Claude Hariton ("Hariton Dec.") at Ex. 2 (Division of Bioequivalence request), Ex. 3 (Division of Chemistry request), Exs. 4-5 (responses). Because the FDA has not asked Dabur for further information in this regard, Dabur asserts that the FDA is satisfied with the submission and has made a "scientific determination that sodium succinate is a buffer in Dabur's formulation." Dabur Brf. at 3.

Plaintiffs dispute Dabur's assertion that succinic acid acts as a buffer. According to

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[4]There appears to be no dispute that Dabur's product meets all of the other limitations of the asserted claims.

Plaintiff's expert, "Dabur's formulation is no different from oxaliplatin in water because it contains an insufficient amount of excipients to result in a formulation with a meaningfully altered pH, assay or impurity profile over time, indicating no change in overall stability." Declaration of Nicholas Farrell ("Farrell Dec.") ¶ 66. Dr. Farrell states that Dabur's formulation performs "the same function as the claimed oxaliplatin in water, in the same way, and with the same result." *Id.* Dr. Farrell points to data from Dabur's own experiments and concludes that "Dabur's added excipients are not present in sufficient quantity to have an effect on the stability of an oxaliplatin-in-water solution." *Id.* ¶ 86.

Reviewing the evidence submitted in support of and in response to Dabur's motion,[5] the Court finds that there exist a genuine fact issue as to whether the succinic acid Dabur adds to its oxaliplatin formulation functions as a buffer or whether, like the spatula in *Norian*, it is merely an irrelevant additive. Consequently, Dabur's motion for summary judgment of noninfringement of the '988 patent shall be denied.

C. Fact Issues Preclude Summary Judgment as to '961 Patent

Sanofi asserts that Dabur infringes the '961 patent under the doctrine of equivalents, and, contrary to Dabur's contentions, the Court finds application of the doctrine is not precluded here. "An accused device that does not literally infringe a claim may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused device either literally or

[5]By way of a letter dated March 10, 2010, Plaintiffs asked the Court to consider in further opposition to Dabur's motion certain deposition testimony of Defendant's expert Dr. Cherian. The deposition took place on July 17, 2009. Because Dr. Cherian's deposition was not taken until after this motion was fully briefed and, further, Plaintiffs did not proffer this evidence until eight months after the deposition date, the Court has not considered the testimony in connection with this motion.

equivalently." *Amgen Inc. v. F. Hoffman-LA Roche Ltd*, 580 F.3d 1340, 1382 (Fed. Cir. 2009) (quoting *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1459 (Fed. Cir. 1998) (en banc)). "The essential inquiry under the doctrine of equivalents is whether 'the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention.'" *Wavetronix LLC v. EIS Electronic Integrated Systems*, 573 F.3d 1343, 1360 (Fed. Cir. 2009) (quoting *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40, 117 S. Ct. 1040, 137 L. Ed.2d 146 (1997)).

The Federal Circuit applies two articulations of the test for equivalence. *Voda v. Cordis Corp*., 536 F.3d 1311, 1326 (Fed. Cir. 2008) (citing *Warner-Jenkinson*, 520 U.S. at 40, 117 S.Ct. 1040 (explaining that different phrasings of the test for equivalence may be "more suitable to different cases, depending on their particular facts"). First, there is the insubstantial differences test, under which "[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial." *Id.* (quoting *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004). Second, there is the the function-way-result test, under which an element in the accused device is equivalent to a claim limitation if it "performs substantially the same function in substantially the same way to obtain substantially the same result." *Id.* (quoting *Schoell v. Regal Marine Indus., Inc*., 247 F.3d 1202, 1209-10 (Fed. Cir. 2001)).

Importantly, as with literal infringement, infringement by equivalents is a question of fact. *Warner-Jenkinson Co., Inc.*, 520 U.S. at 38. Here, Dabur contends it does not infringe because it does not use sodium sulfide and/or potassium iodide in its process and, further, because it does not perform the process of the '961 patent in the claimed sequence of steps. Evidence produced

by Dabur shows, for example, that neither sodium sulfide nor potassium iodide are part of Dabur's production process. *See* Hariton Dec., Ex. 1. Plaintiffs, on the other hand, argue that the Dabur's use of sodium sulfide in its process perform the same function that the sodium iodide and/or potassium iodide performs in claim 1 of the '961 patent. For example, according to Plaintiffs' expert, documents relating to experiments performed by Dabur show that Dabur's use of sodium sulfide "perform[s] the same function --allowing the removal of silver and other impurities -- in substantially the same way -- by forming highly insoluble compounds that can be removed by filtration -- with the same result -- an oxaliplatin compound that is substantially free of impurities." Farrell Dec. ¶ 52. Plaintiff further argues that claim 1 does not require a specific sequence because changing the sequence in the manner performed by Dabur does not alter the result.

Having reviewed the evidence submitted by the parties, the Court finds that there are disputed issues of material fact that preclude summary judgment for either party on the question of whether there is infringement here under the doctrine of equivalents. Accordingly, Dabur's motion and Plaintiffs' cross motions shall be denied.

III. Conclusion

For the reasons above, Dabur's motion for summary judgment of noninfringement of the '988 patent is denied. Dabur's motion for summary judgment of noninfringement of the '961 patent and Plaintiff's cross-motion for infringement are also denied. An appropriate Order accompanies this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J

Dated: March 18, 2010